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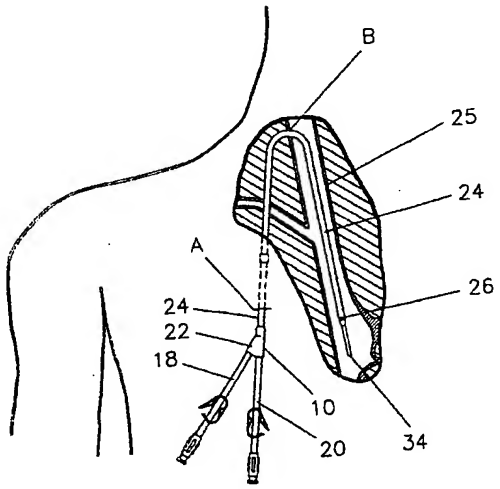
(54) Title: BLOOD TREATMENT CATHETER AND METHOD



(57) Abstract: Disclosed are various embodiments of a hemo-dialysis catheter (10) in which the aspirating port at the end of the aspirating tube (20) is distal of the infusion port or ports (26a/26b) at the end of the infusion lumen (11). The infusion port or ports are arranged circumferentially so that the infused filtered blood is a substantially 360° jet of fluid with a substantial radial component. This jet of fluid serves to abrade the occlusive material that is composed of fibrin and other components that grows down along the outer wall of the catheter that would otherwise tend to block off the ports. Stopping occlusion growth at the zone of the infusion ports prevents further growth distally to the aspirating port and protects the aspirating port from being blocked by the growth of occlusion.

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BLOOD TREATMENT CATHETER AND METHOD

Background Of The Invention

This invention relates in general to blood treatment catheters and more particularly to a design for use in hemo-dialysis in which the occlusion of the distal ports due to fibrin buildup is substantially eliminated.

Hemo-dialysis is the process of mass transfer, in which certain chemical substances, accumulated in the blood because of kidney failure, are transferred from the blood across a semi permeable dialysis membrane to a balanced salt solution. The efficiency of a hemo-dialysis procedure depends on the amount of blood brought into contact with the dialysis membrane. A flow of 250 milliliters of blood per minute under a pressure gradient of 100 millimeters of mercury is considered a minimum requirement for adequate dialysis. Over the past several years, flow rate between 350 milliliters per minute and 400 milliliters per minute have become common.

At the place where the catheter is inserted into the patient, the body reacts by creating a sheath of material that includes fibrin and other materials that grow down the outer wall of the catheter from the point of insertion in the vein. This material is referred to herein as occlusive material. This occlusive material when it grows down to the site of ports, and most particularly the aspirating port, tends to block the ports rendering the catheter essentially useless.

Accordingly, it is the primary object of this invention to create a catheter design that substantially eliminates or reduces the build up of occlusion at the infusion and aspirating ports.

Brief Description

In brief, the catheter disclosed has both aspirating and infusion lumens. At a distal zone, the tube carrying the aspirating lumen extends distally of the end of the tube defining the infusion lumen. At its distal end, the infusion lumen is substantially annular around the aspirating tube and has infusion ports that provide emission of fluid over substantially 360° as a jet like emission having a significant radial component. A nose of a built up zone on the outside of the aspirating tube, immediately adjacent to and distal of the exit port from the infusion lumen, provides a wall for the exit port to assure that the jet of fluid exits in a substantially radial direction.

This jet of infusion fluid abrades the occlusion that tends to grow down these catheters from the point of insertion into the patient. Thus the 360° infusion jet prevents such occlusive material not only from clogging the infusion port but also prevents further distal growth along the aspirating tube. This means that occlusion of the end of the aspirating tube by occluding material is avoided.

Definitions.

The term occlusion or occlusive material refers to the well known coating that builds up on the exterior of these catheters. It starts at approximately the point where the catheter is inserted through the vein and builds down along the outside surface of the catheter. This occlusion build up is believed to be composed of a number of materials such as fibrin, and/or muscle cells and/or blood clot.

This invention is addressed to a technique of preventing the occlusion build up from extending down

over the end of the aspirating port or ports and causing the aspirating ports to block.

Infusion and Aspirating Port and Ports.

The preferred embodiments, shown in FIGs. 3 through 6 contain a plurality of infusion exit ports. As discussed in connection with FIG. 7, a design can be provided in which there is a single circumferential exit port. An essential feature is that there is a substantial 360° jet having a substantial radial component which serves to abrade and clear away occlusion that grows down the outer wall of the catheter. The aspirating port, though shown as a single end port can be a plurality of circumferential ports and the term "port" is used to include the multiple port arrangement.

Accordingly, it should be understood herein that the terms "port" or "ports" or "port arrangement" in the specification and claims are used to include a single port and/or a set of ports, such as the ports 26a of FIG. 3 and the ports 26b of FIG. 5.

Brief Description Of The Figures

FIG. 1 is a schematic illustration of the positioning of the hemo-dialysis catheter of this invention through the jugular vein. In FIG. 1, the catheter is inserted into the patient at point A and into the vein at point B.

FIG. 2 is an elevation view of a catheter of this invention showing the infusion tube 18 and aspirating tube 20 combined at juncture 22 to form the main portion 24 of the catheter. Infusion ports 26 are at the distal end of the infusion lumen. Aspirating port 34 is at the distal end of the aspirating tube 20.

FIG. 3 is a larger scale elevation view of the zone around the distal infusion port of an embodiment of the FIG. 2 catheter having a plurality of angled infusion ports 26a.

FIG. 4 is a partial longitudinal sectional view through the FIG. 3 catheter portion.

FIG. 5 is a larger scale elevation view of the zone around the distal infusion port of a second embodiment of the FIG. 2 catheter showing a plurality of arcuate circumferential ports 26b.

FIG. 6 is a partial longitudinal sectional view along the FIG. 5 catheter portion.

FIG. 7 is a longitudinal sectional view of a further embodiment of the FIG. 2 catheter in which the infusion port 26 is substantially a 360° circumferential port.

FIG. 8 is a cross-sectional view along the plane 8-8 of FIG. 7 showing a three chamber section of the circumferential infusion lumen 11 immediately adjacent to the infusion port 26.

FIG. 9 is a schematic illustration of the infusion of filtered blood at the infusion ports of the infusion lumen. FIG. 9 illustrates the umbrella-like shape of the infusion 40 that results from the combined effect of the radial jet of filtered blood from the infusion ports 26b and the downward flow of the patient's blood.

FIG. 10 is a schematic illustration of blood flow into and from the catheter of this invention at the right atrium.

FIG. 11 is an elevation view of a generic showing of the catheter of this invention. It is used to illustrate three embodiments of this invention which differ in the configuration of the infusion and aspirating lumens over the proximal 80 to 90 percent of the catheter that is between the juncture 22 and the infusion port 26.

FIGs. 12A, 12B, 12C and 12D are cross-sectional views along the planes A-A, B-B, C-C and D-D respectively, of FIG. 11 showing a presently preferred embodiment of this invention. These cross-sectional FIGs. show the transition from the semi-circular lumens 11,12 that exist along about eighty percent of the length of the catheter to the coaxial lumen arrangement immediately proximal of the infusion port 26.

FIG. 13 is a cross-sectional view along the plane A-A of FIG. 11 illustrating a further embodiment of this invention showing two shaped lumens 11,12 that exist over at least eighty percent of the length of the catheter. FIGs. 12C and 12D illustrate the transition of the FIG. 13 embodiment to the coaxial lumen arrangement immediately proximal of the infusion port 26.

FIG. 14 is a cross-sectional view along the plane A-A of FIG. 11 illustrating another embodiment of this invention in which the two lumens 11,12 are coaxial along the entire length from the juncture 22 to the infusion port 26. In the FIG. 14 embodiment, the support web shown at FIG. 8 would be employed.

FIG. 15 is a longitudinal sectional view through the connector 22 for the FIGs. 12A-12D embodiment having the substantially semicircular lumens 11 and 12. FIGs. 15A, 15B and 15C are cross-sectional views along the planes A-A; B-B and C-C, respectively, of FIG. 15.

FIG. 16 is a longitudinal sectional view of the connector for the FIG. 14 embodiment in which the lumens 11,12 are concentric from juncture 22 to infusion port 26.

Description Of The Preferred Embodiments

The catheter 10 of this invention has an infusion lumen 11 and an aspirating lumen 12. The distal end 16 of the aspirating lumen extends distally beyond the distal end 14 of the infusion lumen 11.

More particularly with respect to FIGs. 1 and 2, a standard infusion tube 18 and aspirating tube 20 are combined at a juncture 22 to provide a single tube 24 distal of the juncture 22. The tube 24 contains infusion and aspirating lumens. The tube 24 is inserted into a patient at point A and passed into the jugular vein 25 at point B to be positioned at a desired location; often in the right atrium 38 as shown in FIG. 10.

FIGs. 3 and 4 illustrate a presently preferred embodiment of this invention in which the infusion port set 26 is constituted by ten ports 26a each having a major axis at an angle of approximately 45° to a circumferential line through the ports 26a. In this embodiment, each of the ports is approximately 50 mils (0.050 inches) by 20 mils (0.020 inches). These ports 26a are at the distal end of the infusion lumen 11.

As can best be seen in FIG. 4, the infusion lumen 11 is a circumferential lumen around the aspirating lumen 12 in the zone that is immediately proximal of the infusion exit ports 26a. An inner wall 28 defines the aspirating lumen 12. The infusion lumen 11 is defined by the inner wall 28 and the outer wall 30. Each port 26a is a port in the outer wall 30. The outer wall 30 merges into the inner wall 28 at the zone 36. This provides a terminal wall for the infusion lumen 11 and assures that the infusing filtered blood is ejected through the set of ports 26a in a substantially radial direction.

FIGs. 5 and 6 illustrate a modified version of the FIGs. 3 and 4 embodiment. The difference in this embodiment is that the distal infusion exit port 26 is composed of a plurality of circumferential ports 26b. Each of these circumferential ports 26b is approximately 20 mils (0.020 inches) wide.

In one embodiment, six such openings are involved. Each opening covers an arc of about 70°. The two sub-sets of three circumferentially aligned openings are axially spaced from one another by 45 mils (0.045 inches) centerline to centerline. The FIGs. 5 and 6 embodiment is the same as that of FIGs. 3 and 4 including the employment of the buildup section or nose at the zone 36 that serves to provide an end wall for the infusion lumen 11 and that provides an exit passageway that assures the infusing blood will exit in a substantially radial direction.

FIGs. 7 and 8 illustrate a third embodiment of this invention in which the exit port 26 is a 360° circumferential port.

In order to assure that the 360° port is maintained open and to prevent the wall 30 from collapsing onto the wall 28 over a portion of the exit port arrangement, a web design, shown in FIG. 8, is employed at the exit port 26. This web design involves three thin webs 32 which extend from the zone 36 proximally for about three millimeters in the embodiment shown.

The web 32 supports are not required in the design shown in FIGs. 3 through 6. In those designs, the outer wall 30 extends past the ports 26a or 26b to merge into the wall 28 of the aspirating lumen and thus does not require extra support. However, it should be understood that the design of this invention includes an embodiment in which the FIG. 8 web extends the length of the

catheter from junction 22 to infusion exit port 26. Such a design is not presently preferred because it provides a stiffer catheter than do the designs disclosed herein.

In all three of the embodiments shown in FIGs. 3 through 8, the jet of fluid provided at the infusion port 26 serves to prevent buildup of occlusion distal of those ports. It is believed that a key factor is that the occlusion is physically abraded by the jet of fluid.

As shown in highly schematic form in FIG 9, the jet of filtered blood 40 exits from the ports 26b in a radial direction and then as it joins the flow of patient's blood, becomes more axially oriented. As shown in FIG. 9, the occlusion 42 builds up on the outer wall 30 and extends down to the ports 26b where the abrading action of the jet of filtered blood prevents further growth of the occlusion 42.

As shown schematically in FIG. 10, the hemo-dialysis catheter is frequently placed in the right atrium 38. Of the blood flow 46 coming up from the inferior vena cava into the right atrium, a portion 44 is taken in at the aspirating port 34 to be processed and filtered. The filtered blood 40 is returned as a jet from the infusion lumen. This filtered blood 40 joins the blood flow 46 coming down from the superior vena cava into the right atrium to then be circulated throughout the body.

FIG. 10 shows the catheter extending down into the right atrium. The procedure may also be such that the hemo-dialysis catheter is extending up into the right atrium. In such a situation, the infusion would be into blood from the inferior vena cava and the aspiration would be from blood from the superior vena cava. As shown in FIG. 10, the aspirating port can be in the right atrium providing it is positioned to aspirate blood flow from one of the two vena cavas and so that the infusion

is sufficiently distal to provide filtered blood that merges with blood flow from the other vena cava.

A further feature of this invention can best be understood by reference to FIG. 10. A catheter design which places the aspirating port substantially distal of the infusion port 26 provides a device which reduces irritation to the walls of the right atrium 38 when disposed as shown in FIG. 10.

To avoid problems relating to the immediate re-circulation through the filtering system of filtered blood, known types of catheters place the infusion port distal of the aspirating port, maintaining those two ports separated by a relatively small 1.5 to 2.5 centimeters apart. In those designs, the aspirating port is placed in the blood flow 46 in the superior or inferior vena cava. Thus vena cava blood is the source of blood to the aspirating port. The more distal infusion port that provides filtered blood is positioned at the right atrium to supply filter blood to the right ventricle.

The design of this invention has the aspirating tube extend substantially beyond the end of the infusion tube (four centimeters or more) so that the aspirating port 34 can be placed in substantial communication with the blood flow 46 from the inferior vena cava while the filtered blood 40 is supplied to the patient's heart without being partially re-circulated through the aspirating port.

The portion of the aspirating tube that extends distally of the infusion tube has a smaller diameter than the rest of the catheter. This smaller diameter together with its length makes it more flexible and less likely to irritate the walls of the right atrium 38.

Thus the design of this invention reduces immediate re-filtering of filter blood while providing the surgeon with greater choice in the positioning of the catheter while minimizing irritation.

FIG. 11 is a sub-generic illustration of this invention. It is the basis for the disclosure of various specific arrangements of the infusion lumen 11 and aspirating lumen 12 in the tube 24 between the juncture 22 and the infusion port 26. The length of the catheter between juncture 22 and port 26 generally constitutes between 80 and 90 percent of the total catheter length.

FIG. 12A shows a preferred arrangement of the lumens 11 and 12. In this embodiment, the FIG. 12A arrangement exists through about 85% or more of the distance from the juncture 22 to the infusion port 26. This FIG. 12A arrangement involves two substantially semi-circular in cross-section lumens 11 and 12 separated by a partition 48. In order to assure the substantially 360° infusion jet at the infusion port 26, the coaxial arrangement shown in FIG. 12D is desired. To transition from the FIG. 12A arrangement to the FIG. 12D arrangement, the cross-sectional arrangement shown in FIGs. 12B and 12C are employed.

As shown in FIG. 12A, it is generally desirable that the cross-sectional area of the two lumens 11 and 12 be equal to one another. This equality is maintained as much as possible through the transition so that the cross-sectional area of the lumens 11 and 12 at the infusion exit port 26, as shown in FIG. 12D, are approximately equal. This equality of cross-sectional areas is desirable and is maintained in all embodiments of the invention disclosed herein.

The wall thickness of the partitions 48 can be in the range of 10 to 15 mils (0.010 through 0.015) inches).

Approximately eighty percent of the catheter is constituted by the two semi-circular lumen arrangement shown in FIG. 12A. This is a preferred arrangement because there is less blocking of a lumen when the catheter has to bend.

FIG. 13 shows an alternate embodiment of this invention in which the cross-section at A-A of FIG. 11 illustrates shaped lumens 11 and 12 that are substantially equal in a cross-sectional area. The FIG. 13 lumen design transitions to the coaxial design shown in FIG. 12D at the infusion exit port 26 by way of the intermediate arrangement that is shown in FIG. 12C.

FIG. 14 illustrates a further embodiment in which the coaxial design is maintained throughout the tube 24 from juncture 22 to infusion exit port 26. Thus, the FIG. 14 embodiment requires the use of the FIG. 8 web 32 support arrangement over a short distance at the infusion exit port 26.

In the FIG. 14 arrangement, the FIG. 8 web 32 arrangement is limited to a length of three to five millimeters. The use of these radial webs 36 over greater lengths tends to excessively reduce flow through lumen compression when the catheter goes around bends.

FIG. 15 is a longitudinal section illustrating the manner in which the FIG. 12 semi-circular lumens 11 and 12 arrangement is achieved where the infusion tube 18 and aspirating tube 20 are joined. Specifically, as shown in FIG. 15C, the two lumens 11 and 12 become part of the juncture 22. As shown in FIG. 15B, these two lumens are shaped into the approximately semi-circular modes desired. As shown in FIG. 15A, a wall 24 is provided to define these two lumens 11 and 12. This wall 24 is the outer tube 24.

The juncture 22 for the shaped lumens of FIG. 13 would be in all respects like that of FIG. 15 except for the curvature of the lumens at the cross-sections A-A and B-B.

FIG. 16 is a longitudinal sectional view of the juncture 22, similar to that of FIG. 15, showing the arrangement to provide the FIG. 14 co-axial lumen design.

What We Claim Is:

1. A catheter comprising:

an aspirating lumen and an infusion lumen,

said aspirating lumen terminating distally from the distal end of said infusion lumen,

said infusion lumen in communication with a distal exit port arrangement to provide emission of fluid from said infusion lumen over substantially 360 degrees as a jet of fluid having a substantial radial component.

2. The catheter of claim 1 wherein: said circumferential jet of infusion fluid provides a barrier to minimize occlusion buildup on the catheter surface at, and distal to, said infusion exit port.

3. The catheter of claim 1 wherein, in a zone adjacent to said infusion exit port arrangement, said infusion lumen is circumferentially deployed around said aspirating lumen.

4. The catheter of claim 2 wherein, in a zone adjacent to said infusion exit port arrangement, said infusion lumen is circumferentially deployed around said aspirating lumen.

5. The catheter of claim 3 further comprising:

a proximal portion of said aspirating and infusion lumens are each substantially semi-circular lumens, and

a transition zone between said proximal portion and said zone adjacent to said infusion exit port arrangement.

6. The catheter of claim 4 further comprising:

a proximal portion of said aspirating and infusion lumens are each substantially semi-circular lumens, and

a transition zone between said proximal portion and said zone adjacent to said infusion exit port.

7. The catheter of claim 1 further comprising:

a built-up zone on the outer surface of the catheter at a position adjacent to and distal of said infusion exit port arrangement to provide a wall at said exit port that assures a substantial radial component for fluid flow from said exit port.

8. The catheter of claim 4 further comprising:

a built-up zone on the outer surface of the catheter at a position adjacent to and distal of said infusion exit port arrangement to provide a wall at said exit port that assures a substantial radial component for fluid flow from said exit port.

9. The catheter of claim 6 further comprising:

a built-up zone on the outer surface of the catheter at a position adjacent to and distal of said infusion exit port arrangement to provide a wall at said exit port that assures a substantial radial component for fluid flow from said exit port.

10. The catheter of claim 1 wherein said infusion exit port arrangement comprises a plurality of ports arranged to provide said substantially 360 degree jet of fluid.

11. The catheter of claim 2 wherein said infusion exit port arrangement comprises a plurality of ports arranged to provide said substantially 360 degree jet of fluid.

12. The catheter of claim 4 wherein said infusion exit port arrangement comprises a plurality of ports arranged to provide said substantially 360 degree jet of fluid.

13. The catheter of claim 9 wherein said infusion exit port arrangement comprises a plurality of ports arranged to provide said substantially 360 degree jet of fluid.

14. A catheter comprising:

an aspirating lumen and an infusion lumen, said aspirating lumen terminating distally from the distal end of said infusion lumen.

15. The catheter of claim 14 wherein said aspirating lumen extends at least four centimeters past said distal end of said infusion lumen.

16. The catheter of claim 14 wherein the termination of said infusion lumen is an annulus around said aspirating lumen.

17. The catheter of claim 14 wherein said infusion lumen terminates at an infusion port and said aspirating lumen terminates at an aspirating port.

18. The method of blood treatment comprising the steps of:

aspirating blood at a first location in a patient's vascular system, and

infusing treated blood in a substantial 360 degree jet having a radial component at a second location in a patient's vascular system, said infusing second location being proximal of said aspirating first location.

19. The method of claim 18 further comprising the step of: eroding occlusion buildup at the site of said infusing.

20. The method of claim 18 wherein said first and second locations are at least four centimeters apart.

21. The method of claim 20 further comprising the step of: eroding occlusion buildup at the site of said infusing.

22. The method of claim 18 wherein:

said step of aspirating is through an end port of an aspirating lumen and said step of infusing is through an end port of an infusion lumen.

23. The method of claim 21 wherein:

said step of aspirating is through an end port of an aspirating lumen and said step of infusing is through an end port of an infusion lumen.

24. The method of blood treatment employing a catheter having an aspirating lumen with an aspirating port and an infusion lumen having an infusion port to provide filtered blood comprising the steps of:

positioning the infusion port proximally of the aspirating port, and

infusing treated blood into the patient as a jet extending substantially 360 degrees around the catheter.

25. In the method of aspirating blood through an aspirating port, filtering the blood and infusing the filtered blood back into a patient through an infusion port, the improvement comprising the steps of:

infusing the filtered blood in a substantially 360 degree radial jet from the catheter, and

providing the aspirating port at a position distal of said infusion port,

whereby occlusive material that grows along the outer surface of the catheter is abraded at the infusion port and further distal growth is prevented.

26. The method of blood treatment comprising the steps of:

aspirating blood through a catheter at a first location in the patient's vascular system, and

infusing treated blood through a catheter at a second location in the patient's vascular system,

said first location aspirating blood flow from one of said inferior or superior vena cava and said second location infusing treated blood into blood flow from the other one of said inferior or superior vena cava,

said infusing second location on said catheter being proximal of said aspirating first location on said catheter by sufficient distance to provide said steps of aspirating and infusing from and to blood flow of different segments of the vena cava.

27. The method of claim 26 wherein said first and second locations are spaced apart by at least four centimeters.

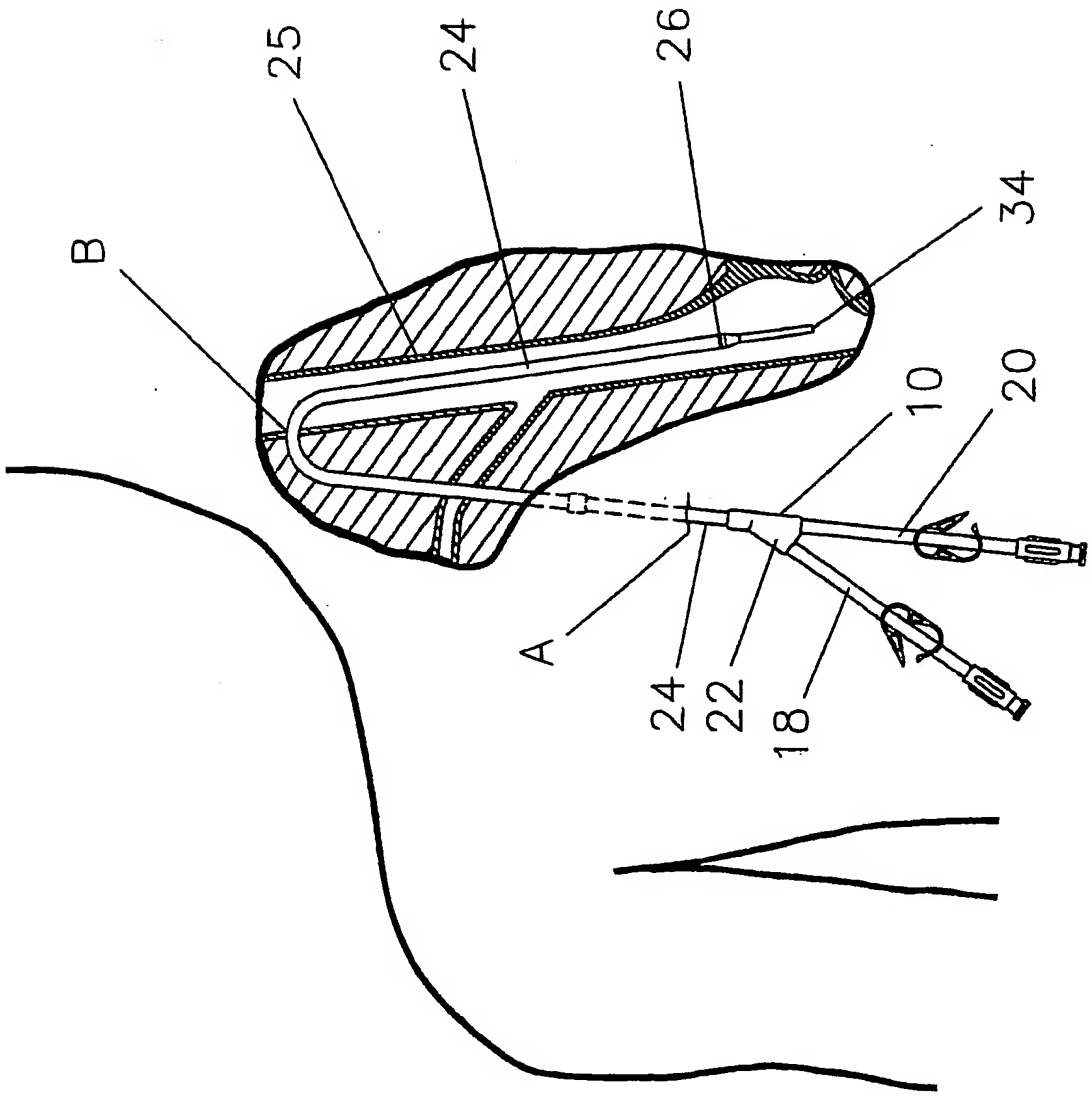

Fig. 1

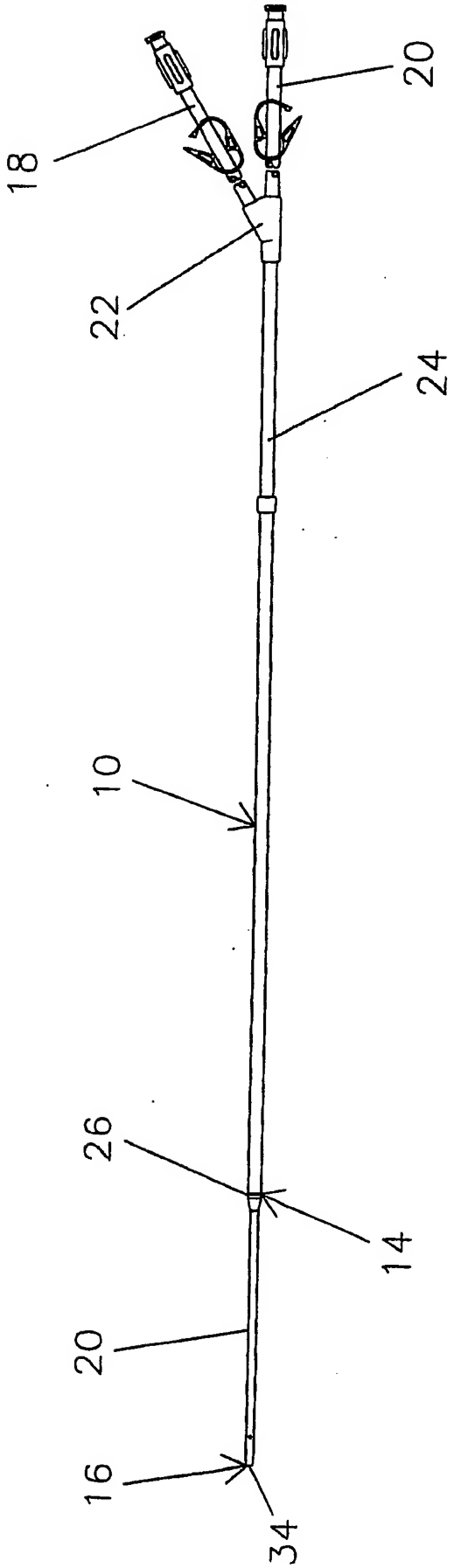

Fig. 2

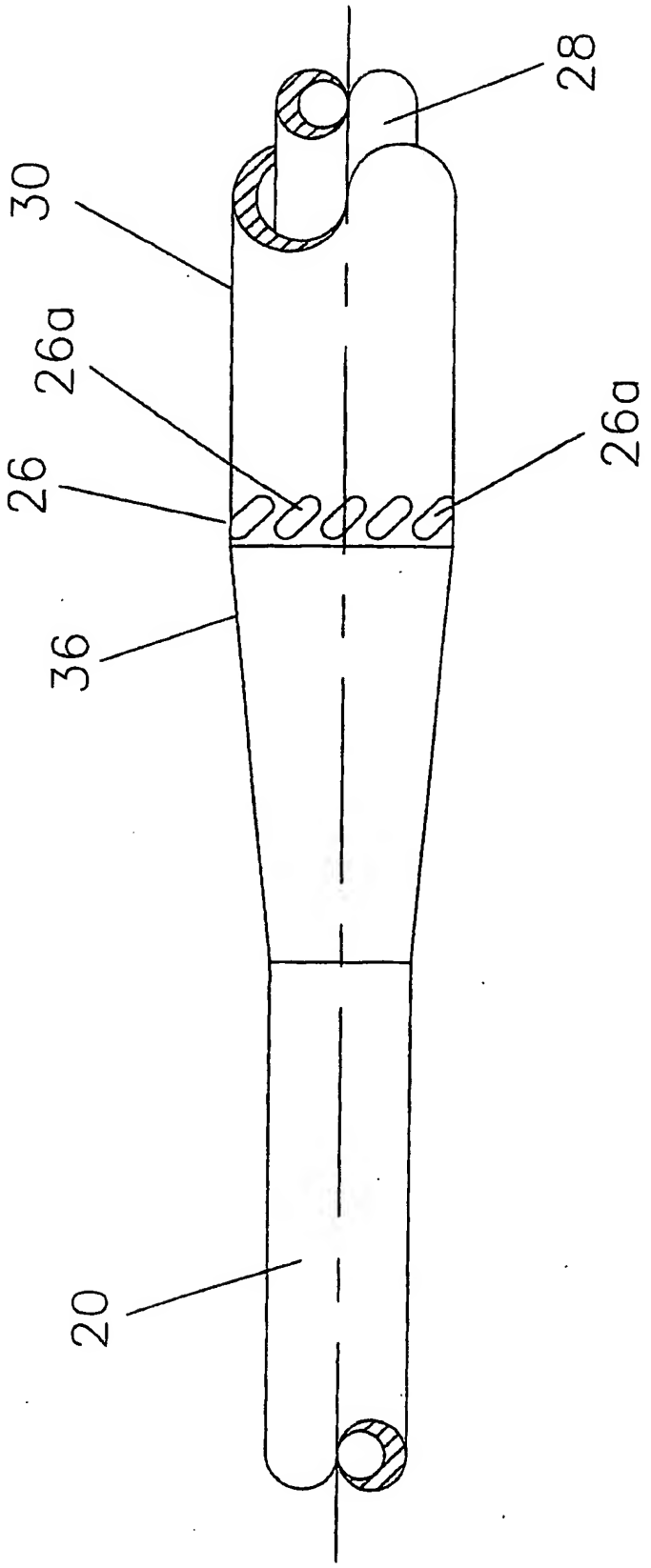

Fig. 3

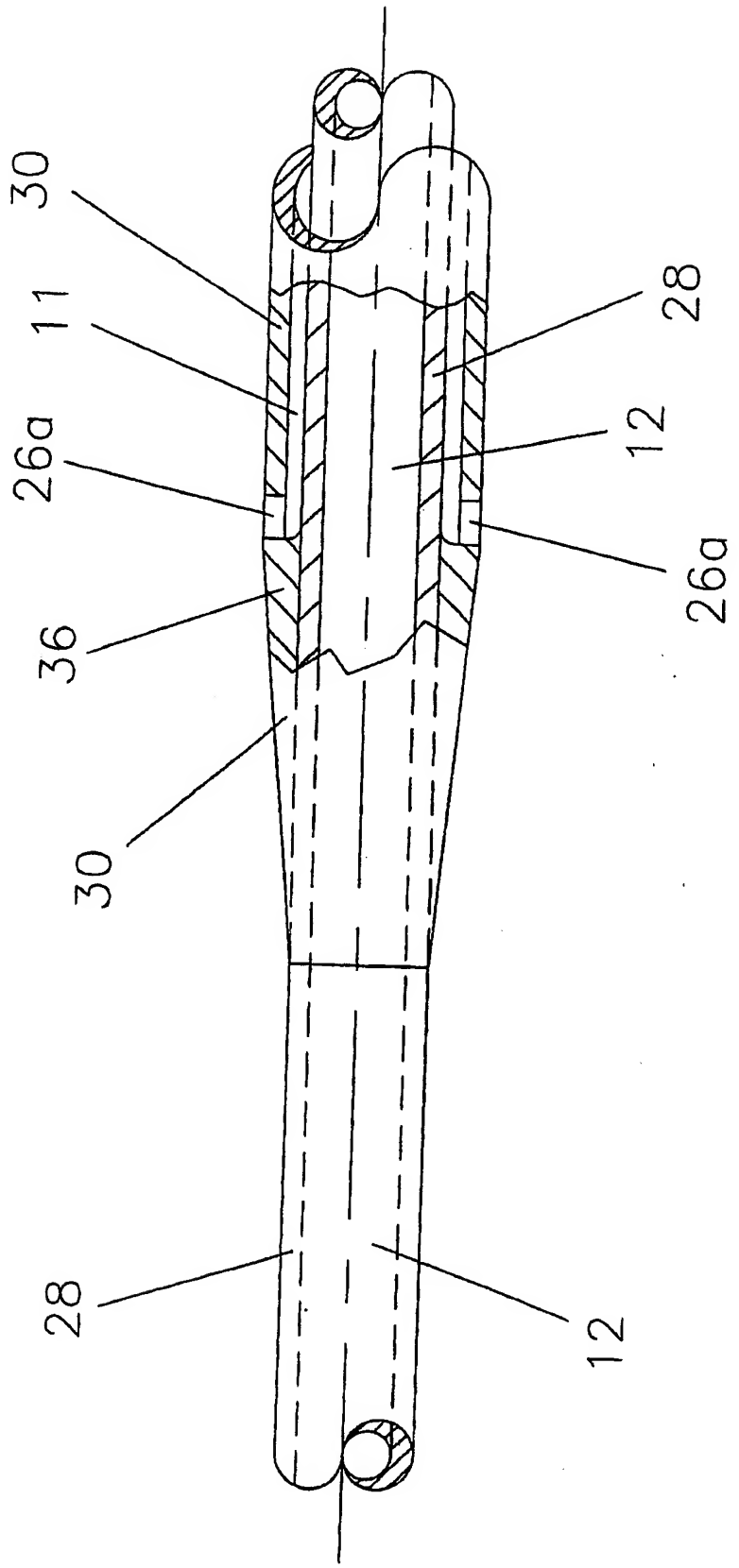

Fig. 4

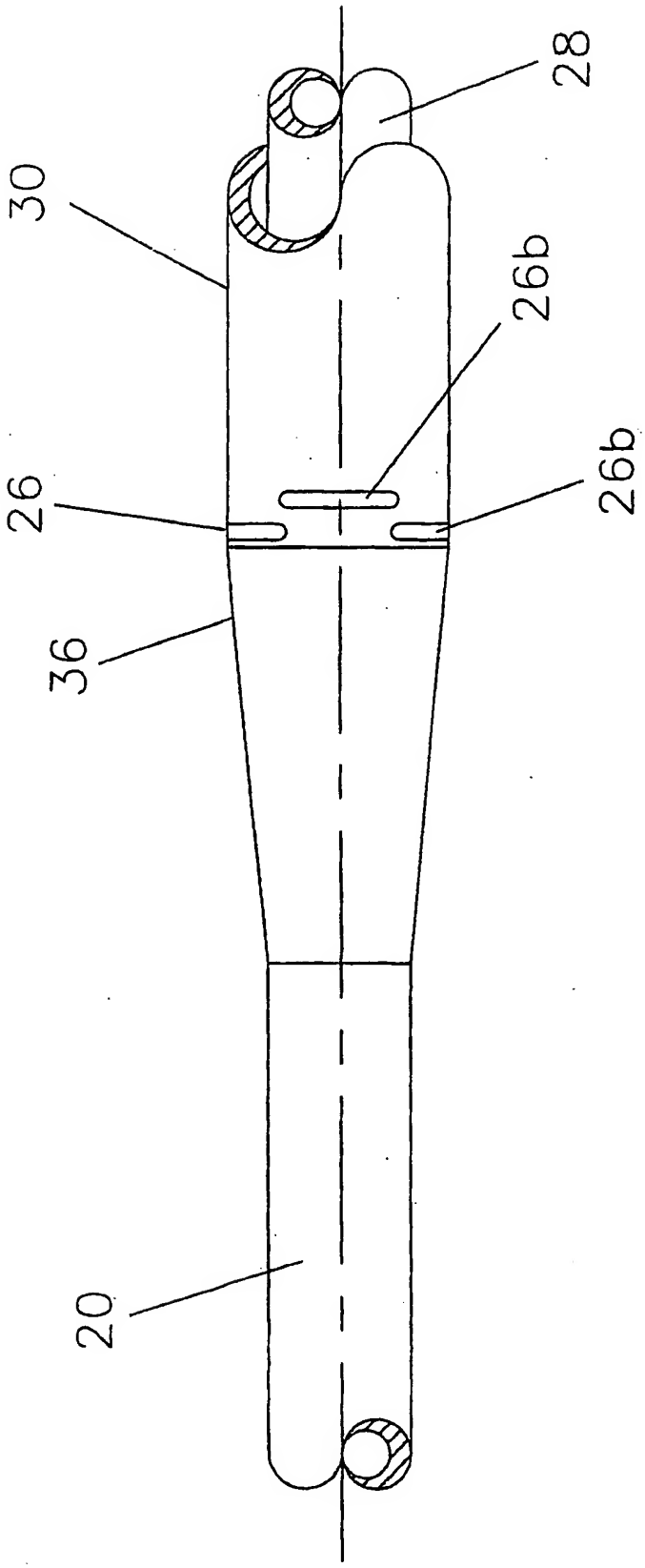

Fig. 5

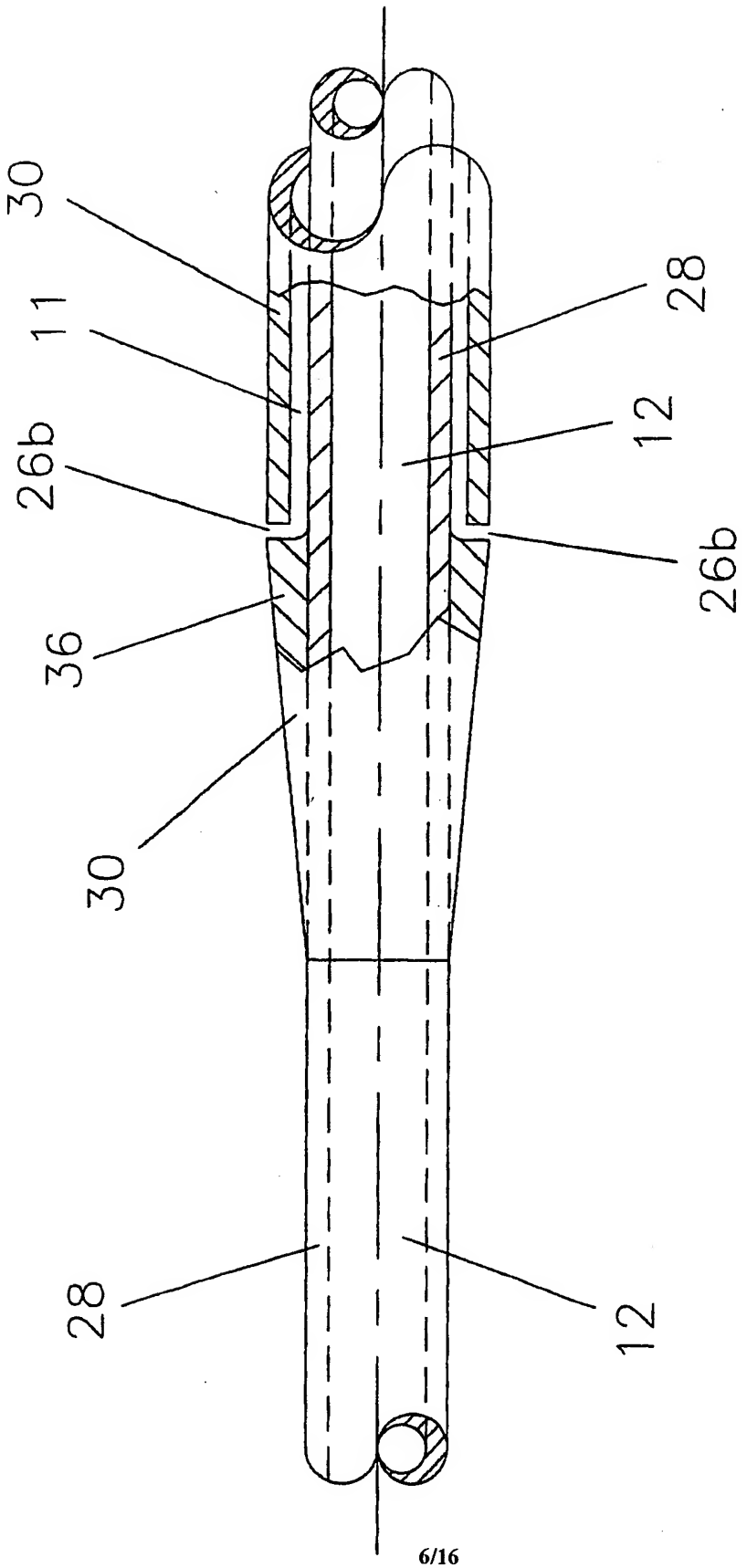

Fig. 6

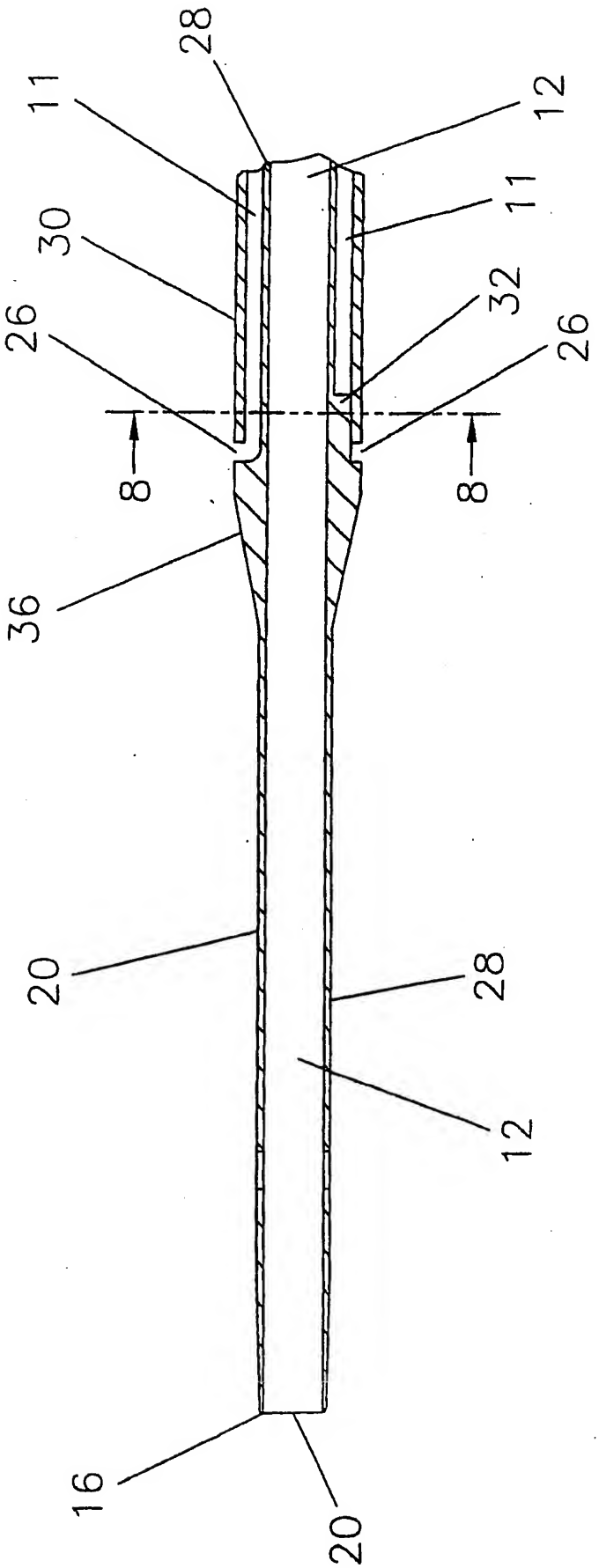

Fig. 7

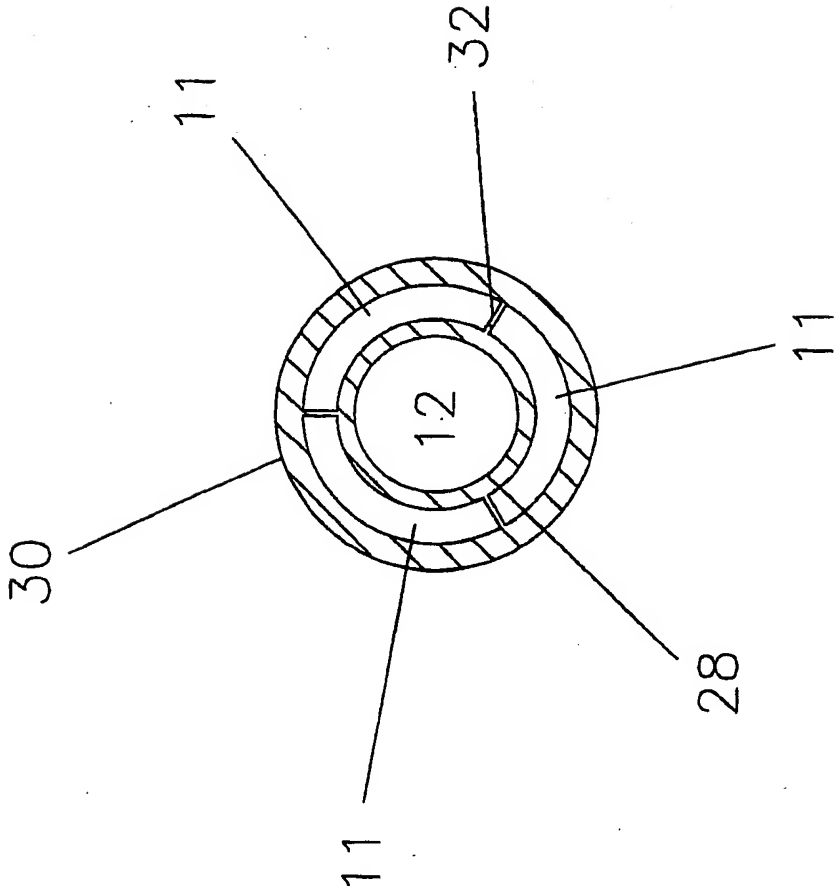

Fig. 8

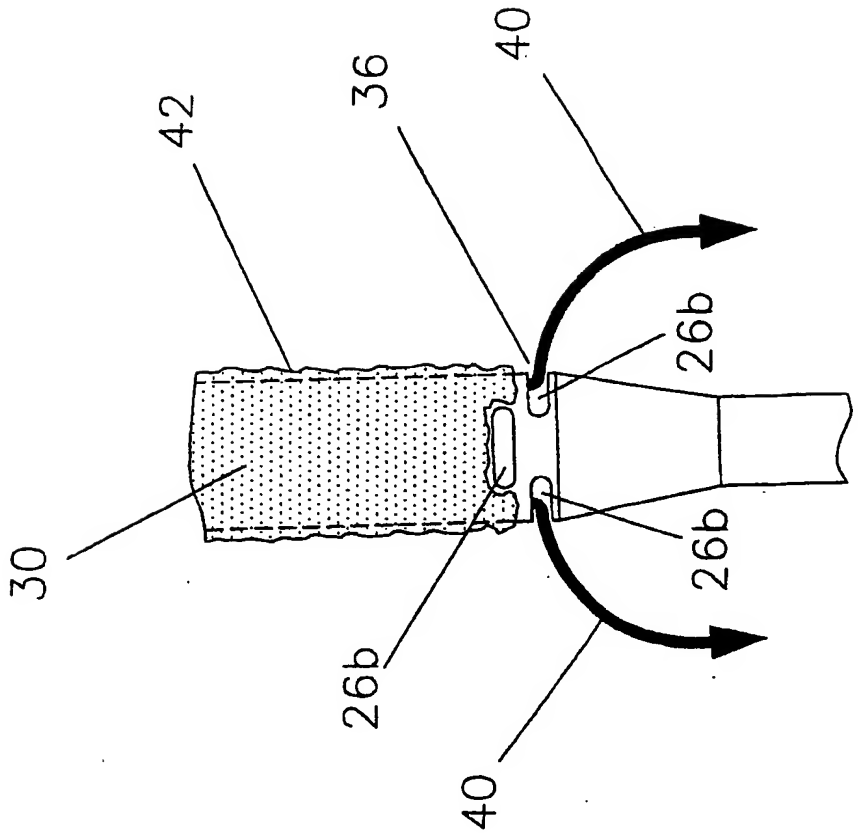

Fig. 9

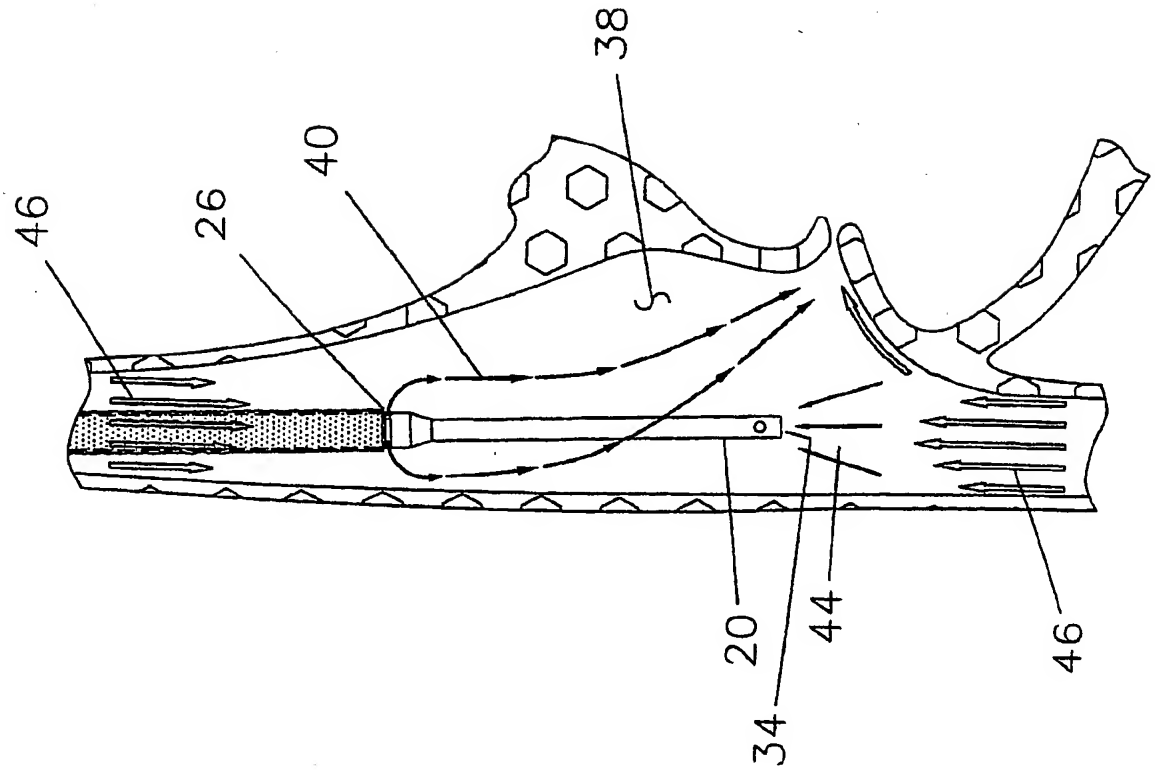

Fig. 10

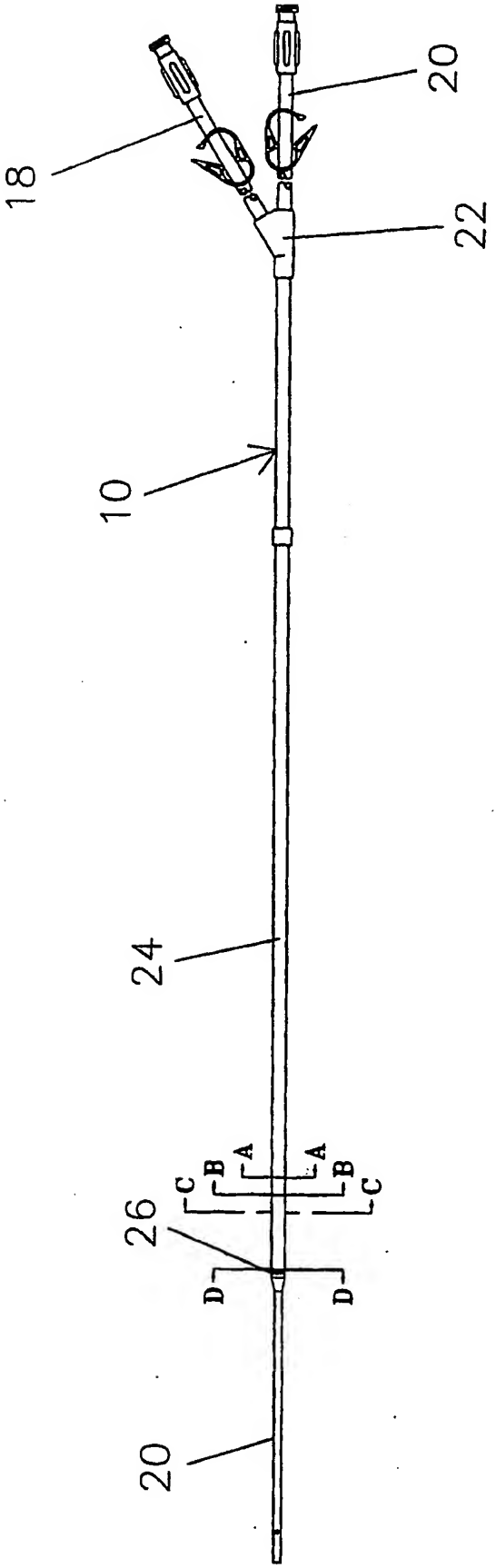

Fig. 11

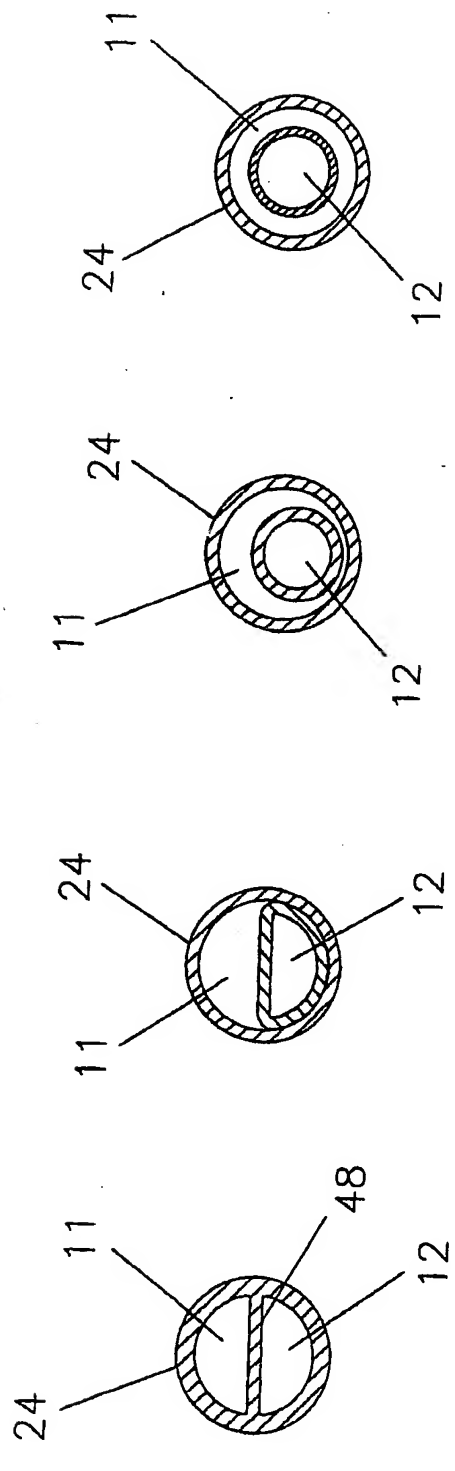

Fig.12D

Fig.12C

Fig.12B

Fig.12A

Fig. 12

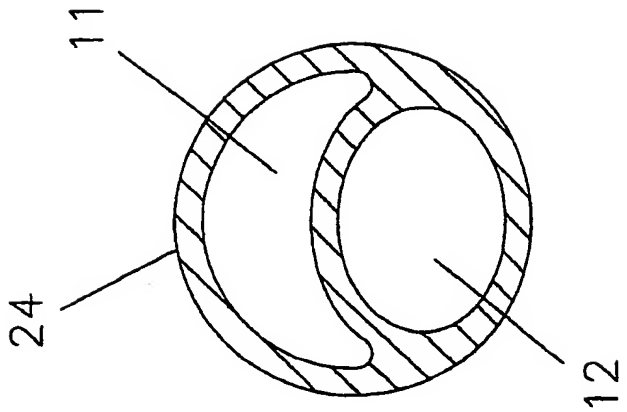

Fig. 13

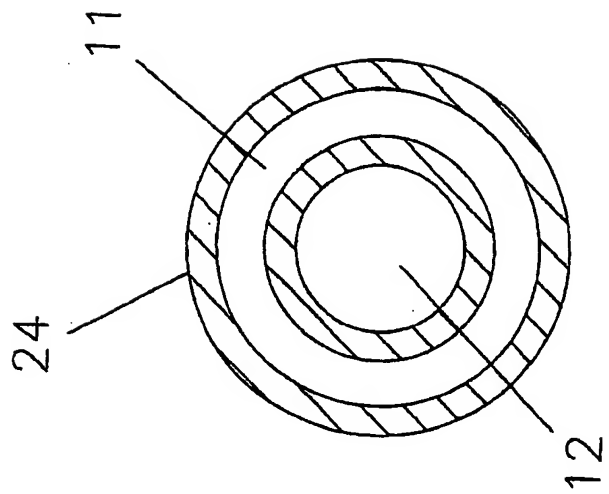

Fig. 14

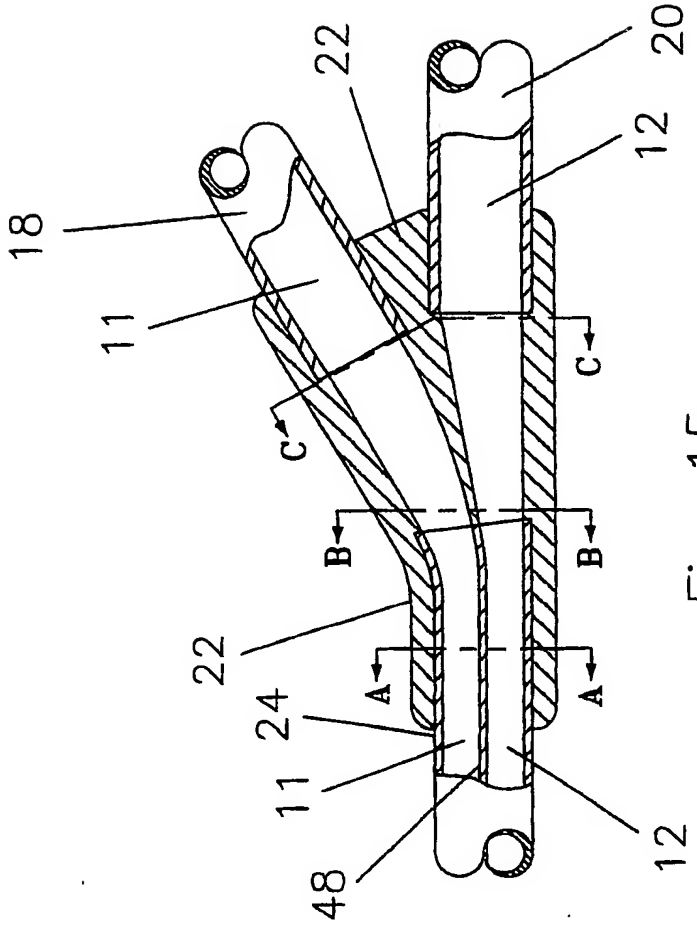

Fig. 15

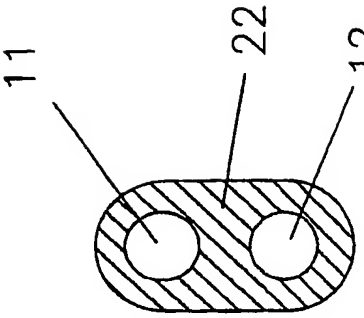

Fig.15C

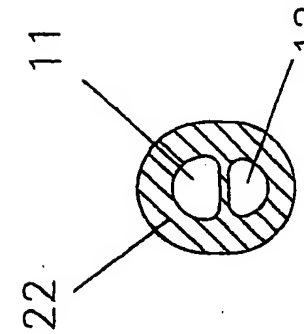

Fig.15B

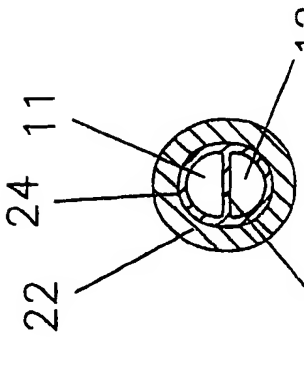

Fig.15A

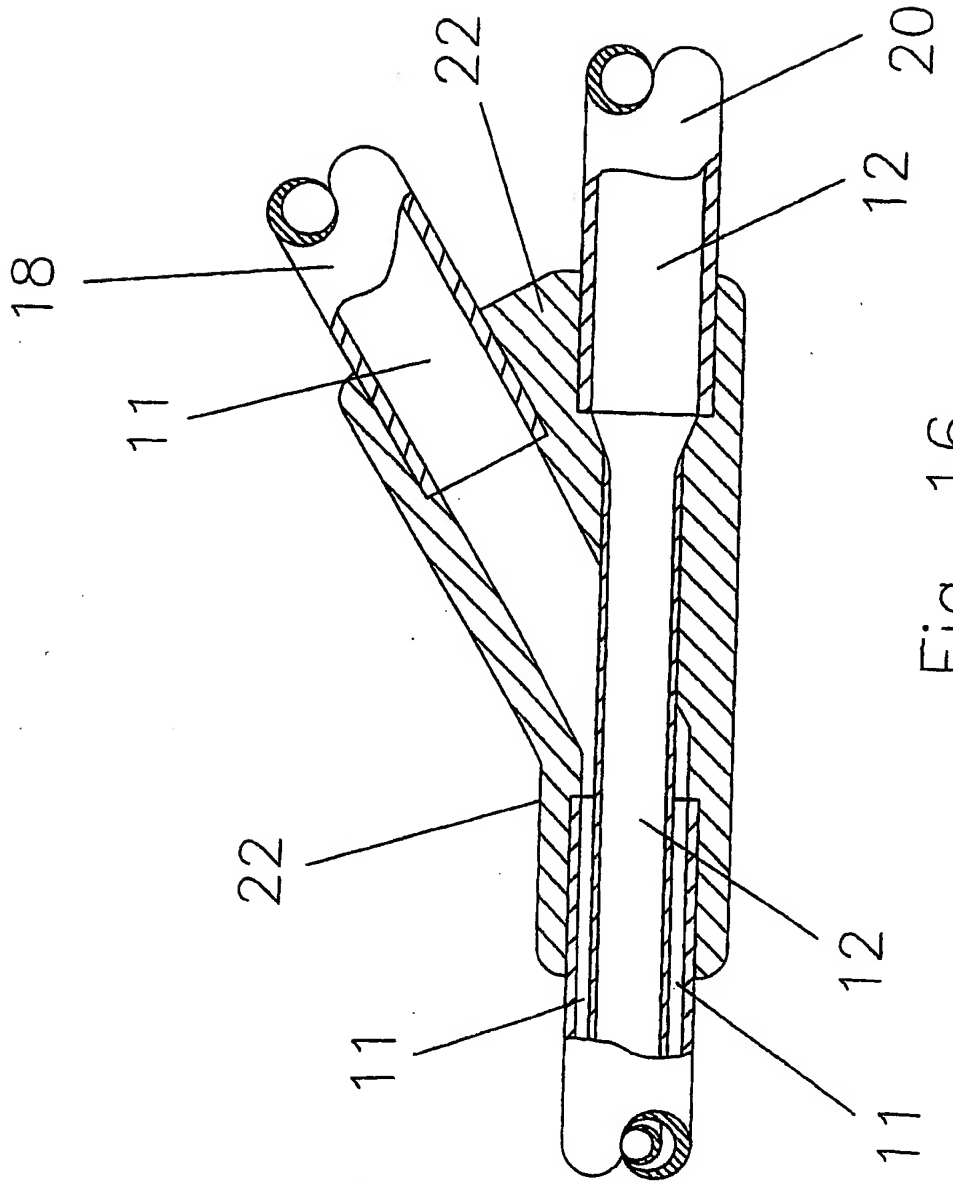

Fig. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/10042

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 37/00, 3/00; B01D 11/00
US CL : 604/4.01, 5.01,6.16, 43, 93.01, 95.02; 210/646

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : Please See Continuation Sheet

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 5,209,723 A (TWARDOWSKI et al.) 11 May 1993, entire document.	14, 15, 17 — 1-13, 16, 18-25
X — Y	US 5,718,692 A (SCHON et al.) 17 February 1998, enire document.	1, 2, 10, 11, 14-18, 20, 22-24 — 3-9, 12, 13, 19, 21, 25
X — Y	US 5,807,311 A (PALESTRANT) 15 September 1998, entire document.	14, 15, 17 — 1-13, 16, 18-25
X — Y	US 5,947,953 A (ASH et al.) 07 September 1999, entire document.	1, 2, 10, 11, 14-18, 20, 22-24 — 3-9, 12, 13, 19, 21, 25

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
13 June 2003 (13.06.2003)

Date of mailing of the international search report
12 AUG 2003

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INTERNATIONAL SEARCH REPORT

International application No.
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C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 6,001,079 A (POURCHEZ) 14 December 1999, entire document.	1, 2, 10, 11, 14-18, 20, 22-24 ——— 3-9, 12, 13, 19, 21, 25
X,P — Y,P	US 6,517,529 B1 (QUINN) 11 February 2003, entire document.	1, 2, 10, 11, 14-18, 20, 22-24 ——— 3-9, 12, 13, 19, 21, 25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/10042

Continuation of B. FIELDS SEARCHED Item 1:
604/4.01, 5.01,6.16, 43, 93.01, 95.02, 5.02-5.04, 19, 28, 500, 507, 508, 94.01, 95.01, 264, 523, 534, 539; 210/646, 645; 138/111, 115-117; 600/581